

REMARKS

Reconsideration of the present application is requested. Claims 192-197 and 209-211 were subject to substantive review. The claims were subject to a provisional double patenting rejection in view of several co-pending applications. Since it is believed that the present case is in condition for allowance, the provisional double patenting rejection will be moot. The pending claims were also rejected as anticipated by the patent of Brantigan. For the reasons set forth below, it is believed that Brantigan neither anticipates nor renders obvious Applicants' claimed invention.

Claim 192 recited introducing the intermediate elements consecutively. While it is believed that this language contemplates individually introducing each of the intermediate elements, Applicants have amended independent claim 192 to clarify that aspect of the method step. This amendment should overcome the apparent misapplication of Brantigan as an anticipatory reference.

It is of course known that in order for Brantigan to anticipate it must disclose each and every element or step of the claimed invention. First, Brantigan fails to disclose a method for interbody fusion incorporating a plurality of intermediate elements, each being of substantially similar configuration. It was suggested that the configuration in FIG. 12 of Brantigan showing two implants 21 between top and bottom implants satisfies this limitation of Applicants' claim 192. However, it is clear from the figure and from the associated description (col. 6, lines 41-52) that this embodiment of Brantigan is for replacement of a vertebral body and adjacent discs. The construction in FIG. 12 is not an interbody fusion, which occurs between intact vertebral bodies. Brantigan does depict an interbody fusion embodiment in FIGS. 10, 11, 13 and 14. In those embodiments, either one or two implants are positioned within the interbody space. The oval implants are optimally sized to match the height of an average disc. Col. 2, lines 19-22. There is no disclosure of a plurality of intermediate elements - or any intermediate elements for that matter – between the two interbody fusion implants 11 depicted in FIG. 10.

Second, Brantigan neither discloses nor contemplates introducing the intermediate elements between previously inserted top and bottom elements, as recited in claim 192. It is clear that the insertion direction for the implants is perpendicular to the grooves and ridges on the upper and lower faces of the Brantigan implants. As shown in FIG. 13, an insertion tool 73 engages the threaded hole 13. As shown in FIG. 4, the threaded hole 13 is oriented

perpendicular to the ridges 12 that interdigitate with ridges on an adjacent plug or that engage the vertebral endplates. The presence of the ridges shows that Brantigan did not contemplate inserting one plug between two previously inserted implants. It is apparent that if the Brantigan implants were introduced as recited in claim 192 the ridges would interdigitate, thereby preventing further advance of the implant into the patient. If the ridges 12 were aligned parallel to the direction of insertion (as represented by the tool hole 13), the ridges would fail to perform an essential purpose of the Brantigan device, namely for "gripping the vertebrae to resist expulsion," (col. 3, line 67 – col. 4, line 2) and "to prevent slippage" (col. 5, lines 22-26). Brantigan even provides for a connecting bar 15 that has a height conforming to the total height of a stack of implants. Col. 4, lines 38-49; FIGS. 4-5. The connecting bar is intended to prevent shifting of the stack (col. 4, lines 44-47), which can only happen along the length of the ridges.

Instead, the Brantigan prosthetic implants are stacked outside the patient's body for insertion as a combined stack. In particular, Brantigan states, "During surgery, the spinal column is stretched to regain any lost disc space ... This stretches the remaining disc tissues and as illustrated in FIGS. 13 and 14, the plugs of this invention such as the plugs **11 or a stack of the plugs**, are inserted into the opened up disc space ...". Col. 6, lines 59-68 (emphasis added). Thus, as dictated by the ridges on the faces of the stacked plugs, the space or opening must be large enough for the stack to be inserted *in toto*. There is no insertion or introduction of intermediate implants between previously positioned implants in Brantigan. The embodiments in Brantigan incorporating the connecting bar 15 clearly require that the implants be stacked prior to insertion, otherwise the bar could not be seated in the interior grooves 14 of the implants.

Brantigan also fails to disclose or contemplate consecutively positioning a plurality of intermediate elements between previously positioned top and bottom elements. Again, since Brantigan only describes inserting a completed stack into the space, there is nothing in Brantigan to disclose or suggest consecutive insertion of any elements, let alone a plurality of intermediate elements. The language added to claim 192 is also absent from Brantigan, since this reference neither discloses nor contemplates individually introducing each of the plurality of intermediate elements.

The same argument holds for the step in claim 192 in which the consecutive introduction of the intermediate elements relatively moves the top and bottom elements apart

to distract the upper and lower vertebral bodies. As explained above, Brantigan requires that the space be pre-distracted or stretched so that the stack can be inserted into the "opened up disc space." Col. 6, lines 59-68. Since Brantigan neither discloses nor contemplates consecutive introduction of any implants, it certainly cannot anticipate a limitation in which consecutive introduction moves the top and bottom elements apart and performs distraction on the interbody space.

Brantigan fails to disclose every step recited in independent claim 192, and therefore is inapplicable as an anticipatory reference. At best it can be said that Brantigan discloses a structure that includes a stack of elements in which the height of the stack can be determined prior to insertion. Brantigan does not disclose or contemplate the steps of Applicants' claim 192. Even if hindsight is applied to reconfigure the Brantigan plugs to at least be able to be used in the manner recited in claim 192, it would be necessary to remove or reorient the ridges on the implants. However, removing or reorienting the ridges would completely frustrate the avowed purposes of the Brantigan device, such as achieving interbody fusion without cutting grooves into the vertebrae (col. 1, lines 44-47), incorporating ridged surfaces to bite into the vertebral bone (col. 1, lines 56-58), resisting expulsion (col. 2, lines 67-68), forming valleys to facilitate bone ingrowth (col. 3, line 1) and interdigitate with each other for stacking (col. 3, line 2).

Of course, where the prior art reference clearly requires modification to meet claim limitations, that reference cannot be said to anticipate. Moreover, it is improper to modify the prior art in a way that eliminates or frustrates expressed purposes of the prior art invention simply to reject the pending claims. In the present case, Brantigan cannot anticipate Applicants' claims because the devices and methods disclosed in Brantigan must be modified in order to meet the limitations of claim 192. The Office Action does not provide any *prima facie* case for obviousness, but as explained above, any modification to Brantigan necessary to meet Applicants' claims would destroy the functionality of the Brantigan implants. Thus, it can be concluded that Applicants' claim 192 is neither anticipated nor rendered obvious by the Brantigan reference.

It can also be pointed out that dependent claims 196 and 197 recite limitations not found in Brantigan, namely that the top or bottom elements have an area greater than any of the intermediate elements. It is apparent from the figures in Brantigan that all of the implants are identical with identical areas. Even if certain of the Brantigan implants may be regarded

as top, bottom and intermediate elements, there is no disclosure of differently sized implants relative to others in the same stack. Moreover, given that the Brantigan implants are ring-like, any size differential between adjacent implants would destroy the ability to stack the implants, since the smaller area implant would be swallowed up within the hollow interior of the larger area implant.

Applicants have introduced new independent claim 212 and its dependent claims 213-224. Independent claim 212 is similar to previously cancelled claim 98, but with modifications to the step of consecutively introducing the elements. In particular, new claim 212 identifies the elements as being similar configured and individually consecutively introduced between opposing vertebrae. In addition, new claim 212 includes the limitation that as an element is inserted it moves at least one previously inserted element to a different position, similar to the limitation of previously cancelled claim 99.

Like claim 192, new claim 212 includes the limitation of individually consecutively introduced elements. As discussed above, Brantigan fails to disclose or contemplate individual consecutive introduction of its implants. Moreover, since Brantigan requires pre-distraction of the insertion site and pre-stacking of the implants, it cannot meet the limitation of claim 212 that previously inserted elements are moved to different positions upon insertion of a new element. Thus, new claim 212 and its dependent claims 213-224 are believed to be allowable over Brantigan.

It can also be pointed out that the dependent claims include limitations that are not, and cannot, be found in Brantigan. For instance, new dependent claim 214 recites that the step of accessing the intradiscal space between vertebral bodies occurs through an elongated access channel. There is no disclosure in Brantigan of such an access channel, nor would there be any such disclosure because of the nature of the implants and surgical procedure described in that reference. In claims 216 and 218-221 the elements are defined as wafers. The Brantigan implants are not wafers but hollow plugs. The Brantigan implants do not incorporate flat leading and trailing surfaces, first because the Brantigan implants are not configured for individual consecutive insertion and second because the implants require the interlocking ridges. Similarly, the Brantigan implants do not incorporate beveled leading or trailing surfaces. Brantigan also fails to disclose or contemplate the step of monitoring the tension in the annulus, since Brantigan only contemplates pre-distraction of the space.

In view of the foregoing arguments it is believed that the present claims 192-197 and 209-224 are patentable over Brantigan. Brantigan fails to anticipate Applicants' claims because it lacks all the recited elements. Brantigan cannot render Applicants' claims obvious because any necessary hindsight changes to bring Brantigan in conformance with Applicants' claimed invention would destroy the features, benefits and functionality of the Brantigan implants as touted in that reference. Consequently, action toward a Notice of Allowance is hereby requested.

Respectfully submitted,

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